Operational Aspects of Terminating the Doxazosin Arm of the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT)

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ABSTRACT: The Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) is a randomized, practice-based trial sponsored by the National Heart, Lung, and Blood Institute (NHLBI). The double-blind, active-controlled component of ALLHAT was designed to determine whether the rate of the primary outcome—a composite of fatal coronary heart disease and nonfatal myocardial infarction—differs between diuretic (chlorthalidone) treatment and each of three other classes of antihypertensive drugs: a calcium antagonist (amlodipine), an angiotensin-converting enzyme inhibitor (lisinopril), and an alpha-adrenergic blocker (doxazosin) in high-risk hypertensive persons ages 55 years and older ($n = 42,448$). In addition, 10,377 ALLHAT participants with mild to moderate hypercholesterolemia were also enrolled in a randomized,
open-label trial designed to determine whether lowering serum LDL cholesterol with an HMG CoA reductase inhibitor (pravastatin) will reduce all-cause mortality as compared to a control group receiving “usual care.” In January 2000, an independent data review committee recommended discontinuing the doxazosin treatment arm. The NHLBI director promptly accepted the recommendation. This article discusses the steps involved in the orderly closeout of one arm of ALLHAT and the dissemination of trial results. These steps included provisional preparations; the actual decision process; establishing a timetable; forming a transition committee; preparing materials and instructions; informing 65 trial officers and coordinators, 628 active clinics and satellite locations, 313 institutional review boards, over 42,000 patients, and the general public; reporting detailed trial results; and monitoring the closeout process. Control Clin Trials 2001;22:29±41 © Elsevier Science Inc. 2001

KEY WORDS: Clinical trials, closeout, large simple trial, early termination

INTRODUCTION

Early termination of a clinical trial requires addressing many issues in an orderly and expeditious manner. Much has been written about monitoring rules and guidelines for early termination of trials [1–9] and about the mechanics of actually closing out such studies [10–14]. All the operational approaches in these references agree that termination should be regarded as a major trial phase along with protocol development, recruitment, and follow-up and that anticipation of early closure of part or all of a protocol and careful planning with consideration of patient safety and study goals are keys to successful trial closure. In each early termination, activities were intensified, challenges compounded, and other trial activities temporarily disrupted [12–14]. However, little information is available about termination of large, simple trials in general and about early termination in particular.

The Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) is a randomized, practice-based trial sponsored by the National Heart, Lung, and Blood Institute (NHLBI) [15]. The double-blind, active-controlled component of ALLHAT was designed to determine whether the rate of the primary outcome—a composite of fatal coronary heart disease (CHD) and nonfatal myocardial infarction (MI)—differs between diuretic (chlorthalidone) treatment and each of three other classes of antihypertensive drugs: a calcium antagonist (amlodipine), an angiotensin-converting enzyme inhibitor (lisinopril), and an alpha-adrenergic blocker (doxazosin) in high-risk hypertensive persons ages 55 years and older (n = 42,448). In addition, 10,377 ALLHAT participants with mild to moderate hypercholesterolemia were enrolled in a randomized, open-label trial designed to determine whether lowering serum LDL cholesterol with an HMG CoA reductase inhibitor (pravastatin) will reduce all-cause mortality as compared with a control group receiving “usual care.” Figure 1 illustrates the study design.

Patient enrollment began in February 1994. Recruitment for the antihypertensive trial ended successfully in January 1998, and recruitment for the lipid trial ended successfully in May 1998. Active follow-up for both components is scheduled to end in March 2002. Six hundred twenty-three clinical sites randomized 42,448 participants; several additional sites were later opened to accommodate patient transfers. Nine regional teams monitor and assist the sites in their regions during recruitment and follow-up. To monitor patient safety and study
progress, a Data and Safety Monitoring Board (DSMB) was appointed by the NHLBI. ALLHAT’s study protocol included monitoring guidelines [16].

THE DECISION TO TERMINATE THE DOXAZOSIN ARM

At the July 1999 DSMB meeting, the board noted that compared with doxazosin, chlorthalidone yielded an essentially equal risk of CHD death and nonfatal MI (the primary endpoint), but reduced the risk of combined cardiovascular disease (CVD) events (a specified secondary endpoint including the primary CHD endpoint, angina pectoris, coronary revascularization, congestive heart failure [CHF], stroke, and peripheral arterial disease), particularly CHF. Because CHF is considered a “soft” endpoint, additional data analyses were conducted at the board’s request. Because these analyses appeared to support the main findings and the likelihood of observing a significant difference for the primary outcome by the scheduled end of the trial was very low, the Steering Committee chair and representatives of the ALLHAT NHLBI Project Office and the Clinical Trials Center met several months prior to the January 2000 DSMB meeting to discuss these trends and prepare a timetable for possible closeout. Discussions began regarding the required materials, including a letter notifying the investigators, letters to the participants, and a short paper describing the pertinent results, as well as other materials.

Also, three individuals from the ALLHAT regional teams were nominated to participate on the closeout team with the Steering Committee chair and representatives from the NHLBI and Clinical Trials Center. Because the nominees previously had been blinded to the data, they were not notified of their selection prior to the decision to terminate the doxazosin arm.

By the time of the January 2000 DSMB meeting, letters to the principal investigators and the participants, as well as a short paper describing the comparison of doxazosin and chlorthalidone, had been drafted.

Data reviews took place on January 6 and 21, 2000. After the second review, a recommendation was issued for termination of the doxazosin arm based on previously described observations. The NHLBI director accepted that recommendation on January 24, 2000, setting in motion the activities described in this paper [17].
THE TIMETABLE FOR CLOSEOUT OF THE DOXAZOSIN ARM

The timetable for the closeout of the doxazosin arm was framed around three dates:

1. Release of information to the Steering Committee and regional teams—February 3, 2000
2. Press release from NHLBI—March 8, 2000
3. Presentation at the American College of Cardiology meeting—March 15, 2000

The timeline is further described in Table 1.

SELECTING THE TRANSITION TEAM AND INTERIM PREPARATIONS

Upon the acceptance of the recommendation, the NHLBI Project Office notified the Clinical Trials Center. The three previously identified members of the regional teams were asked to participate on a transition team under the condition of confidentiality. Fortunately, the Steering Committee and regional teams were already scheduled to meet on February 3–4, 2000 for a routine face-to-face meeting. Two agendas were prepared: one for distribution in advance of the meeting that did not mention the closeout of the doxazosin arm and another agenda that included details on the data, the decision, the activities, and a timeline for transition.

The first conference call for the transition team was held on January 28, 2000. The call included a short session on the unblinded results for the benefit of the three new team members. Draft materials were reviewed and detailed plans were made regarding investigator notification, participant notification, collection of transition-phase data, continuity of antihypertensive care for participants assigned to doxazosin, central collection of the blinded doxazosin capsules, and publication of the results. Several more conference calls were held in the 10 days prior to the Steering Committee meeting. The team also met face to face prior to this meeting to finalize details of the plan as well as its presentation. Also, first contacts were made regarding expedited publication of the results, and a timeline was confirmed for the remaining activities (see Table 1).

Because chlorthalidone was found to be better at preventing combined CVD events (a specified secondary endpoint), particularly CHF, compared to doxazosin, open-label chlorthalidone was to be provided for use in participants who would be discontinuing doxazosin. However, use of open-label chlorthalidone was not mandatory, and investigators could prescribe alternative antihypertensive therapy at their discretion. Treatment could include the open-label chlorthalidone, and/or any of the step 2 and step 3 medications provided by ALLHAT (atenolol, clonidine, reserpine, hydralazine); other antihypertensive medications could be prescribed, but would be at the participant’s expense. These treatment recommendations followed those of the Sixth Report of the Joint National Committee on Hypertension [18], although the final treatment decision was up to the investigator. Guidelines were also provided in the document “Frequently Asked Questions (FAQ) for Regional and Study Coordinators” regarding what to advise for participants on open-label alpha blockers for benign prostatic hypertrophy.
Table 1  Summary Timeline of Doxazosin Closeout

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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</thead>
<tbody>
<tr>
<td>1/6/00 and 1/21/00</td>
<td>Data review meetings</td>
</tr>
<tr>
<td>1/24/00</td>
<td>Acceptance of recommendation to discontinue doxazosin arm</td>
</tr>
<tr>
<td>1/28/00</td>
<td>First conference call meeting with transition committee</td>
</tr>
<tr>
<td>2/3/00</td>
<td>Face-to-face meeting with transition committee</td>
</tr>
<tr>
<td>2/4/00</td>
<td>Announcement to ALLHAT Steering Committee</td>
</tr>
<tr>
<td>2/8/00</td>
<td>Conference call with transition committee</td>
</tr>
<tr>
<td>2/11/00</td>
<td>Closeout materials finalized</td>
</tr>
<tr>
<td>2/14/00</td>
<td>Steering Committee conference call to discuss results paper</td>
</tr>
<tr>
<td>2/15–17/00</td>
<td>Orientation conference calls with regional teams</td>
</tr>
<tr>
<td>2/16–18/00</td>
<td>Packages to sites: principal investigator notification, institutional review board packet, instructions, letters to patients, lists of patients, postage-paid envelopes, fax-back sheets</td>
</tr>
<tr>
<td>2/18/00</td>
<td>Paper submitted for expedited journal review</td>
</tr>
<tr>
<td>2/28/00</td>
<td>Deadline for sites to mail letters to participants</td>
</tr>
<tr>
<td>2/29/00–3/3/00</td>
<td>Transition forms, patient histories, certificates, and instructions to sites</td>
</tr>
<tr>
<td>3/8/00</td>
<td>National Heart, Lung, and Blood Institute press release</td>
</tr>
<tr>
<td>3/15/00</td>
<td>American College of Cardiology presentation</td>
</tr>
<tr>
<td>5/25/00</td>
<td>Deadline for transition form submission to Clinical Trials Center</td>
</tr>
</tbody>
</table>

Participants assigned to doxazosin and not enrolled in the lipid trial (i.e., participants discontinuing their ALLHAT participation) who were recruited from among patients in ALLHAT investigators’ practices were provided a 4-month supply of antihypertensive medication from ALLHAT and continued with their antihypertensive treatment in the context of routine nonstudy medical care. Other participants who were assigned to doxazosin and not enrolled in the lipid trial could receive a 4-month supply of antihypertensive medication from ALLHAT and returned to other primary caregivers for subsequent antihypertensive treatment and usual routine follow-up.

Pfizer Inc. provided doxazosin for ALLHAT. A few days prior to the Steering Committee meeting, NHLBI representatives informed Pfizer and the Food and Drug Administration of the decision to terminate the doxazosin arm.

**NOTIFICATION OF THE STEERING COMMITTEE AND REGIONAL TEAMS**

The confidential results and transition plan were revealed to the Steering Committee on February 3, 2000. By the end of the meeting, the letters, closeout form, and instructions were finalized, and discussions began with the ALLHAT Drug Distribution Center regarding a supply of open-label chlorthalidone. After the meeting, the regional teams were allowed to notify their sites that important information would be forthcoming and should be given priority handling, without divulging the content of the information.

By mid-February, after necessary translations into Spanish, instructions to clinics had been finalized and copied, and personal letters had been printed for over 40,000 participants. Each regional team participated in a telephone
NOTIFICATION OF CLINICAL SITES, INSTITUTIONAL REVIEW BOARDS, AND TRIAL PARTICIPANTS

During the third week of February, investigator notification letters (see Appendix A), participant notification letters (see Appendix B), and other transition materials (see Appendix C) were mailed to all of the clinical sites and satellite locations by overnight courier. A fax-back sheet, with key dates in an easy-to-track format, was included so that the Clinical Trials Center could identify sites that had not received the materials. After 1 week, a list of nonresponding sites was provided to the regional teams for follow-up. Letters to the participants were to be mailed by the sites to the participants by February 28, 2000. Several of the activities required that the activity be dated and initialled at the sites and faxed to the Clinical Trials Center to verify completion.

One to 2 weeks after distribution of the initial kit, a second kit was distributed that included carbonless copies of the transition form, certificates of appreciation and study histories for the participants assigned to doxazosin and not in the lipid trial, and copies of letters that could be sent to other nonstudy primary care providers who may be associated with the participants. Each site also received several bottles of open-label chlorthalidone as previously described. Participant newsletters that included additional information about the results and how they affect participation in ALLHAT were also provided.

PRESS RELEASE, PRESENTATION TO PUBLIC SCIENTIFIC COMMUNITY, PUBLICATION

Several factors came into play regarding the release of the doxazosin-chlorthalidone comparison results. Considerations included the importance of quickly getting new and important scientific information into the hands of clinicians, as well as the need to have this information presented in a balanced way with a proper interpretation of the study data as a result of a peer-review process.

The manuscript of the results was approved by the Steering Committee during a conference call on February 14, 2000 and submitted to the Journal of the American Medical Association (JAMA). JAMA accepted the request for expedited peer review, and the paper was reviewed, revised, and received final approval by March 10. It was published on the World Wide Web in JAMA Express on April 5 and was in print in the April 19, 2000 issue [17].

During the peer-review process, the NHLBI prepared and distributed a press release that was embargoed until March 8 to accommodate the timetable for mailing the letters to participants. This release was also provided to the Steering Committee, DSMB, regional teams, and clinical sites. On March 15, the results were presented at the American College of Cardiology late-breaking results session.
MONITORING THE CLOSEOUT PHASE, LOSSES TO FOLLOW-UP, AND DOCUMENTATION OF STUDY EVENTS

Due to the critical role that the regional teams play in communication with and monitoring of the clinical sites, each region was provided with a list of participant identification numbers at each of their sites and their antihypertensive and lipid-lowering treatment assignments as previously described. In addition, the Clinical Trials Center provided the regions with lists of clinics not responding regarding receipt of the package and/or mailing the letters to the participants. Those clinics were followed very closely by the regional teams. Regional teams scheduled visits to some sites to facilitate completion of transition visits, remove doxazosin bottle codes from drug inventory, and at some very large sites, to help prepare the letters for mailing.

All transition forms were to be completed and closeout forms received at the Clinical Trials Center by May 25, 2000. As of that date, about 78% of the closeout forms were on file at the Clinical Trials Center, and as of the end of July 2000, 85% of the closeout forms were on file. The sites and regions received lists of pending transition visits until all were completed.

Because ALLHAT is a very large trial being conducted in a variety of settings, often in busy practitioners’ offices, finding lost participants presents more of a challenge than in the more traditional trial setting. Even after the transition phase for participants assigned to doxazosin is formally complete, it is expected that the search will continue for some participants classified as lost to follow-up to determine vital status. These searches will utilize various computer databases in addition to specialized searches through the Health Care Finance Administration, the Social Security Administration, and the Veterans Administration.

In addition, efforts continued to obtain documentation on study events that were still pending when the recommendation was made to terminate the doxazosin arm. Because all participants assigned to chlorthalidone, lisinopril, or amlodipine, as well as participants assigned to doxazosin and in the lipid trial, will continue to be followed, events continue to be reported and documented as usual for those participants.

The published analyses were based on the data as of December 3, 1999 and not on data from the closeout forms [17]. Censoring dates were based on the last known follow-up prior to this date. This information formed the basis of the review committee’s recommendation to discontinue the doxazosin arm. The final paper on the doxazosin-chlorthalidone comparison will include events occurring on or before February 15, 2000, when the results were released to the clinical sites. Thus, the final analyses will include about 10 additional weeks of follow-up.

Oversight of other aspects of the overall ALLHAT trial could not be set aside during this period. The key comparisons for the other two antihypertensive treatment arms (lisinopril to chlorthalidone and amlodipine to chlorthalidone) and the lipid trial continued, and all routinely generated study reports (not only the reports on which the termination was based) had to be modified quickly to accommodate further routine monitoring.
CONCLUSIONS

ALLHAT has a partial factorial trial design with four antihypertensive treatment arms and two lipid treatment arms. Only the doxazosin treatment arm was terminated, leaving the remainder of the antihypertensive treatment arms and the lipid trial to continue as usual. ALLHAT’s transition phase for the closeout of the doxazosin arm was very successful. We agree with reports from other trial closeouts that indicate that early termination, particularly discontinuation of only part of a trial, is extremely disruptive and usually requires temporary suspension of some normal activities at clinical sites as well as other support centers, the Clinical Trials Center, and the study leadership. The time and effort required are enormous, particularly with only a few months available to implement and complete an effective closeout. Defining the priorities for data release, planning a timeline, and drafting the transition materials prior to the actual decision to terminate were critical to ALLHAT’s success with the termination of the doxazosin arm, as was the commitment to the planning and implementation process from the NHLBI, Steering Committee, Clinical Trials Center, and regional teams.

Because most ALLHAT clinical sites are in a variety of practice settings rather than research-specific settings, the resources available to ALLHAT sites were a particularly important consideration in addition to patient safety and study goals. In such circumstances, materials must be laid out in a step-by-step fashion with clear instructions. All required materials should be provided if possible, down to postage-paid envelopes and clinic return-address labels. (Provision of the postage-paid envelopes was agreed by all parties to be a critical piece of the transition kit.) Fax-back verification from the sites was also important at key points in the closeout process. Comments from the ALLHAT clinical sites and regional teams indicated that the transition kits were complete, clear, and facilitated the transition process.

ALLHAT is scheduled to complete follow-up in March 2002. The planning team for the scheduled conclusion of the study was named in the summer of 2000 and plans will be based on experience gained in the termination of ALLHAT’s doxazosin arm. Our experience in ALLHAT indicates that one cannot start planning closeout too soon, especially for a trial as large as ALLHAT.

Closing out all or part of a protocol involving over 42,000 participants is a huge endeavor. With commitment, both time and financial, from all parties involved, the outcome can be successful.

Financial support for the ALLHAT trial is provided through federal contract N01-HC-35130.

APPENDIX A: LETTER TO INVESTIGATORS

February 16, 2000

Dear ALLHAT Investigator:

We are writing to provide important information concerning the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), which has led to a modification of the protocol. This information is not public at this time and we ask that you keep this confidential until the patients in ALLHAT are informed and the NHLBI publicly releases the results. You should, however, send a copy of this letter to your IRB right away.
Following a review in January, the Director of the National, Heart, Lung, and Blood Institute accepted the recommendation of an independent data review committee. Accordingly, the doxazosin arm is being terminated. The recommendation was based on a very low probability of finding a favorable outcome for the group assigned to doxazosin compared to those assigned to chlorthalidone in the primary endpoint [nonfatal myocardial infarction or coronary heart disease (CHD) death], coupled with a statistically significant 25% higher rate of a secondary endpoint, combined cardiovascular disease (CVD). The higher rate of combined CVD [which includes the primary CHD end point, angina pectoris, coronary revascularization, congestive heart failure (CHF), stroke, and peripheral arterial disease] was driven by a highly significant twofold higher rate of CHF compared with the diuretic arm, but there were trends in the same direction for stroke and some other components. The primary CHD outcome and total mortality were not different between the doxazosin and chlorthalidone arms.

It was determined that participants assigned to doxazosin should be informed of their BP treatment assignment and that the major clinical findings regarding this treatment and its comparison agent, chlorthalidone, be reported as soon as possible. Regarding other comparisons, the DSMB emphasized the crucial importance of continuing the rest of the BP and lipid-lowering components.

In order to communicate appropriate messages about the implications of these results for various participant groups, the Steering Committee has prepared letters and closeout materials for you to use to contact all your ALLHAT patients. The letters, the closeout forms, and the details on what procedures to follow will be provided to you within the next 2 weeks. Only those patients assigned to doxazosin and not in the lipid-lowering trial will be closed out. All other patients will be asked to continue, as the other questions ALLHAT is addressing remain unanswered. Those patients assigned to doxazosin and in the lipid-lowering trial portion of ALLHAT will be offered the use of open-label chlorthalidone, which the study will provide at no cost. All of this will be explained in the material you are to receive. If you have any questions, please contact your Regional Coordinator.

All of us who are conducting ALLHAT greatly appreciate your continued participation as a site principal investigator. You and your patients have already helped to answer one of the questions for which ALLHAT was designed. ALLHAT will continue, since the other questions to be answered by ALLHAT remain of fundamental importance for hypertension treatment. As detailed information is reported to the scientific and wider community, we will keep you fully informed.

Thank you for all your efforts to date and for your continuing diligent participation in ALLHAT.

Sincerely,

Curt Furbeg, MD
Steering Committee Chair
Jackson Wright, MD, PhD
Steering Committee Vice-Chair
APPENDIX B: SAMPLE LETTER FOR PARTICIPANTS ASSIGNED TO DOXAZOSIN AND NOT IN THE LIPID COMPONENT

February 18, 2000

Dear [participant name]:

You have been participating in the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). I am writing to let you know that ALLHAT is about to release its first results.

The purpose of the ALLHAT trial is to compare the ability of four commonly used blood pressure medications to reduce the risk of heart disease, stroke, and early death. All four of the ALLHAT medicines were selected because they are commonly used by doctors when treating patients with high blood pressure and because doctors do not agree on which of the four is better.

When you joined ALLHAT, you were assigned by chance to take one of the four blood pressure medicines. Your safety has been monitored closely throughout the study by an independent panel of experts. During the most recent review, it was determined that the medicine to which you were assigned (doxazosin) appears to be the least effective of the four in preventing heart failure. Although heart failure was not the main focus of the study, the study reviewers have decided that the difference is important enough to notify me and for me to notify you.

It is very important that we meet together to decide on a treatment for your high blood pressure, discuss what the study results mean for you, and to answer questions that you have. This will be your last ALLHAT visit. Please call my clinic by the end of March at the number listed below to make an appointment. DO NOT STOP TAKING YOUR ALLHAT MEDICINE UNTIL WE DECIDE ON THE BEST TREATMENT FOR YOU, BECAUSE THE MEDICINE IS HELPING TO KEEP YOUR BLOOD PRESSURE CONTROLLED. Be sure to bring your ALLHAT medicine to the clinic with you.

All of us who are conducting ALLHAT greatly appreciate your participation, which has helped the study to find out that one of the blood pressure medicines is less effective than the others at preventing heart failure. We still do not know which of the other ALLHAT medicines are best for treating high blood pressure.

Sincerely,

[Principal investigator]

[ALLHAT site contact information]
APPENDIX C: THE TRANSITION KIT

Notification Letter to Principal Investigator
See Appendix A.

Packet for Institutional Review Board
This packet included a short explanation of the enclosures, a copy of the notification letter to the investigators, and samples of the letters to the participants. The packet was intended to be sent to the institutional review board “as is.”

Doxazosin Transition Timeline
To help the sites keep track of all the required tasks, a timetable was provided in a checklist format. Space was provided to enter the date of completion for each item. The form was required to be faxed to the Clinical Trials Center twice: once to verify receipt of the kit and again to report that all letters had been mailed to the participants.

Flowchart
A card stock flowchart summarized closeout requirements based on antihypertensive and lipid-lowering treatment assignment. This easy reference was to be posted in conspicuous locations at the sites.

Patient Lists
Three lists of participants were provided to each site based on antihypertensive and lipid-lowering treatment assignment: (1) assigned to doxazosin and not in the lipid component, (2) assigned to doxazosin and in the lipid component, and (3) not assigned to doxazosin. Each list contained checkboxes for every major step in the closeout process.

Letters to Participants
It was required that a letter be sent to each participant not already reported as deceased, including participants reported as lost or refusing to participate. The letter explained the results and how the results might affect participation in ALLHAT. Letters were color-coded based on the participant’s antihypertensive and lipid-lowering treatment assignment. The letters were printed by the Clinical Trials Center and included the participants’ ID numbers and names, as well as contact information for the site. Principal investigator signatures were recommended but not required. The letter was printed in English on one side, and in Spanish on the other. All letters were to be addressed by site personnel and mailed to the participants by February 28, 2000. A sample letter for participants assigned to doxazosin and not in the lipid trial is provided in Appendix B.
Important Questions and Answers about ALLHAT for Participants

Certain questions were anticipated from participants, families, and other physicians about the results. This document included these questions and appropriate responses and was included with each participant letter. Extra copies were provided to the sites.

Postal Supplies

Postage-paid envelopes were provided as well as return-address labels for the sites.

Instructions for Disposal of Step 1 (Blinded) Doxazosin

A sheet listing all of the step 1 (blinded) doxazosin codes was used as a packing list when returning the bottles to the ALLHAT Drug Distribution Center or faxed to the Drug Distribution Center as verification that the drug was properly disposed of locally.

Transition Form

Several photocopies of the transition form were provided so that visits could start as early as possible. Printed carbonless copies were provided about 2 weeks later.

Frequently Asked Questions (FAQ) for Regional and Study Coordinators

This document provided additional detail and rationale for the regional teams and site staff about the transition timeline and procedures.

Things to Watch For

The document alerted sites to watch for (1) a supply of open-label chlorthalidone, (2) carbonless transition forms, (3) certificates of appreciation and study histories for all participants randomized to doxazosin and not in the lipid trial, (4) copies of letters that could be sent to other primary care providers, and (5) participant newsletters containing more information about the results and how they affect ALLHAT.

REFERENCES


